

§ 74.1206

Water-insoluble matter, not more than 0.2 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
Sulfonated toluidines, total not more than 0.2 percent.
p-Toluidine, not more than 0.0015 percent.
Sum of monosulfonated D&C Green No. 6 and Ext. D&C Violet No. 2, not more than 3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 80 percent.

(c) *Use and restrictions.* (1) D&C Green No. 5 may be safely used to color nylon 66 (the copolymer of adipic acid and hexamethylenediamine) and/or nylon 6[poly-(*ε*-caprolactam)]nonabsorbable surgical sutures for use in general surgery, subject to the following restrictions:

(i) The quantity of color additive does not exceed 0.6 percent by weight of the suture.

(ii) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(iii) If the suture is a new drug, an approved new drug application, under section 505 of the act, is in effect for it.

(2) D&C Green No. 5 may be safely used for coloring drugs generally, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 24284, June 4, 1982; 47 FR 27551, June 25, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.1206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS. Reg. No. 128-80-3).

(b) *Specifications.* The color additive D&C Green No. 6 for use in coloring ex-

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ternally applied drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 2.0 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p-Toluidine, not more than 0.1 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

1-Hydroxy-4-[(4-methylphenyl)amino]-9, 10-anthracenedione, not more than 5.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Green No. 6 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr. 2, 1982; 47 FR 24278, June 4, 1982; 51 FR 9784, Mar. 21, 1986]

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrene-trisulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices: